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EXAMINER

CALAMITA, HEATHER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/605,766
Filing Date: June 28, 2000
Appellant(s): HAWKINS, GEORGE W.

Royal N. Ronning, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 19, 2005 appealing from the Office action mailed May 16, 2005.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

5,945,334	BESEMER et al	8-1999
5,786,439	VAN ANTWERP et al	7-1998
WO 97/10056	COTTINGHAM et al	3-1997
WO 99/19717	BJORNSON et al	4-1999

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Rehman et al. "Immobilization of acrylamide-modified oligonucleotides by co-polymerization" Nucleic Acids Research, vol. 27, no. 2 (January, 1999), pp. 649-655.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 36,37,40,45,47,49 & 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham et al. (WO 97/10056, 03/20/1997).

Cottingham et al. teach an apparatus for performing biological reactions (see whole doc. esp. abstract & figure 4, DNA amplification and probe assay device) comprising a substrate (see page 13 line 3-4 DNA card with bottom and top layer) and an array with biomolecular probes positioned on first surface (see page 10 lines 1-15 teaching an array arrangement of DNA amplification and assay reagents which includes primers and probes spotted on surface) and flexible layer affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 9 & 10 adhesive binding a plastic film) and port (see page 13 line 21 & last line air vent and sample port). The ports extend through flexible layer (see Figure 4 detail 28 & 26). The apparatus taught by Cottingham et al. is inherently watertight, as a port is described for entry of the sample. Cottingham et al. also do not describe sample leakage indicating the sample chamber is watertight (see p. 5 second paragraph). They teach apparatus may further comprise measuring instrument and heated carrier (see figure 13 detail 80, 81 and page 21 first full paragraph).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Rehman et al. (Nucleic Acids Research, January 1999).

The teachings of Cottingham et al. are described previously.

Cottingham et al. do not teach polyacrylamide.

Rehman et al. teach polyacrylamide layer for binding probes (see p. 649, Introduction paragraph 2).

One of ordinary skill in the art would have been motivated to apply polyacrylamide as taught by Rehman et al. (Nucleic Acids Research, January 1999) polyacrylamide to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to immobilize DNA probes at a greater capacity. Rehman et al. (Nucleic Acids Research, January 1999) state that polyacrylamide provides for great probe capacity, density, lower non-specific binding levels and relatively high thermal stability particularly in amplifications of solid phase PCR and hybridization assays (see p. 649, paragraph 2). It would have been prima facie obvious to apply the polyacrylamide as taught by Rehman et al. (Nucleic Acids Research, January 1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) for DNA probe assays in order to increase the hybridization efficiency of the probe reagents.

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Claims 48,50-56 & 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Bjornson et al. (WO 99/19717, 04/22/1999)

The teachings of Cottingham et al. are described previously.

Cottingham do not teach flexible layer with polyester, polypropylene.

Bjornson et al. teach a variety of well known flexible films such as plastics acrylics and polyethylenes of varying widths (see p. 17 line 15-17). Bjornson et al. teach rolling with roller (see figure 5). Bjornson et al. teach adhesives (see page 25 line 9).

One of ordinary skill in the art would have been motivated to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to construct a cover for the reaction and press to ensure a seal of the film. It would have been prima facie obvious to apply rollers and flexible films as taught by Bjornson et al. (WO 99/19717, 04/22/1999) to the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to ensure a sealed layer in Cottingham's device.

Claims 39, 41, 42, 46, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Besemer et al. (USPN 5,945,334, 08/31/1999).

The teachings of Cottingham et al. are described previously.

Cottingham et al. do not teach sample chip and heater

Besemer et al. teach a chip device containing a substrate having an array of probes attached to cavity (see col. 1 line 65- col. 2 line 3 & claims 1 & 2). The body includes two inlets that allow fluids into and through cavity. A seal, plug or any other seal may be provided for each inlet to retain fluid within cavity (see col. 6 line 39). The body is formed by welding two pieces together. Besemer et al.

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also teach heaters may be connected to device (col. 9 line 62). Besemer et al. also teach of variety of surface supports including glass, silicon, Ge, GaAS (see col. 4 line 60-64).

One of ordinary skill in the art would have been motivated to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order perform hybridization assays. Array chips were well known and commonly practiced in the art to perform detection assays. It would have been prima facie obvious to use chips as taught by Besemer et al. (USPN 5,945,334, 08/31/1999) with the device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) in order to perform a plurality of different assays simultaneously.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al. (WO 97/10056, 03/20/1997) in view of Besemer et al. (USPN 5,945,334, 08/31/1999) in further view of Van Antwerp et al. (USPN 5,786,439, 07/28/1998).

The teachings of Cottingham et al. and Besemer et al. are described previously.

Cottingham et al. do not teach the claimed layer of water-soluble compound.

Van Antwerp et al. teach coating the surface of biosensor with uniform hydrogel (see abstract). The hydrogel may be PEG 600 (see claim 10).

One of ordinary skill in the art would have been motivated to apply PEG-600 coatings as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al. (WO 97/10056, 03/20/1997) and Besemer et al. in order to protect the array from interfering chemicals. Antwerp et al state that the hydrogel layer protects from interfering chemicals such as electrolytes and proteins but allows water to pass through to allow the arrays to accurately measure analyte (see column 1 lines 46-50). It would have been prima facie obvious to apply hydrogel as taught by Van Antwerp et al. (USPN 5,786,439, 07/28/1998) to the chip array device as taught by Cottingham et al.

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(WO 97/10056, 03/20/1997) and Besemer et al. in order to allow the array to accurately measure analytes without interference from other chemicals.

(10) Response to Argument

Cottingham Rejection

Issue

A difference in claim interpretation is the crux of the argument over whether the Cottingham publication anticipates the current claims. The current claims are drawn to “An apparatus for performing biological reactions **comprising**.”

A substrate **comprising** two surfaces. On one surface is an array of biomolecular probes. To this surface a flexible layer is attached via an adhesive layer which creates a reaction volume with a port that extends through the flexible layer and into the reaction volume. The issue is whether the claim is open to additional layers or not, particularly Cottingham discloses three separate plastic layers which are held together by a pressure sensitive adhesive between each layer.

Appellant argues because the DNA card disclosed by Cottingham is made of 3 three separate plastic layers it cannot anticipate the instantly claimed invention as the instantly claimed invention is made of only a first and second layer. However the claimed apparatus expressly uses the open “comprising” format, permitting additional elements such as a third layer to be included in the overall apparatus. As will be discussed next, the Federal Circuit in In re Crish, 73 USPQ2d 1364 (Fed. Cir. 2004) directly addresses this issue.

Legal Standard

In making the determination that a claim is anticipated under 35 U.S.C. §102(b) two analytical steps are required. First, the claim language must be interpreted, and the PTO is entitled to give claims their broadest reasonable interpretation. In re Morris, 127 F.3d 1048, 1055 (Fed. Cir. 1997). Secondly, the construed claim must be compared to the prior art reference and the rejection must make factual

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findings that “each and every limitation is found either expressly or inherently in [that] single prior art reference.” Celeritas Techs. Ltd. v. Rockwell Int’l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998).

In the current case, the rejection discussed above provides substantial evidence that Cottingham teaches an apparatus having a substrate comprising two surfaces. On one surface is an array of biomolecular probes. To this surface a flexible layer is attached via an adhesive layer which creates a reaction volume with a port that extends through the flexible layer and into the reaction volume. The argument raised by Appellant is that Cottingham’s apparatus does not anticipate the instant claims because Cottingham’s apparatus is made of 3 layers whereas the instant claims are drawn to an apparatus comprising 2 layers.

The Court in In re Crish directly confronted this issue where a subelement of a claim limited the claim, but the claim also began with the open ended transition term “comprising”. The Federal Circuit noted “The reasonable interpretation of the claims containing both of the terms “comprising” and “consists” is that the term “consists” limits the “said portion” language to the subsequently recited numbered nucleotides, but the earlier term “comprising” means that the claim can include that portion plus other nucleotides.” In re Crish, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004).

Applying this rule to the current situation, it is clear the term “comprising” applied to the apparatus of the instantly claimed invention means the apparatus can also have additional layers or elements. So even if Cottingham has a third layer, in addition to the two layers which anticipate the current claims, Cottingham anticipates these claims because the apparatus components are open, and may include additional elements.

Appellant additionally argues Cottingham does not teach or disclose an array of biomolecular probes positioned in the first surface of the substrate within a reaction volume (or sample chamber) but rather teaches a plurality of sample chambers contained on the Card, each sample chamber containing a single spot or reagent. Cottingham teaches a plurality of sample chambers or an array of discrete sample

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cells. These sample cells contain dried DNA amplification reagents of nucleic acid primers. Nucleic acid primers are biomolecular probes. These nucleic are arrayed discretely on the surface of Cottingham's DNA card (see page 9 lines 7-8 and p. 10 lines 1-2) and Cottingham's DNA card therefore meets the limitation of an array of biomolecular probes positioned in the first surface of the substrate within a reaction volume (or sample chamber). Appellant argues Cottingham fails to teach the chambers are watertight. Appellant is arguing a limitation which is not recited in the claims as currently listed, therefore the issue is moot.

Appellant asserts the use of the open language of "comprising" is immaterial inasmuch as the apparatus claimed contains a substrate with a first and second surface, an adhesive layer and a flexible layer adhered to the first surface by the adhesive layer and Cottingham provides no disclosure or suggestion of the middle layer and indeed the use of the open language of "comprising" does not change this. Appellant asserts Cottingham does not disclose or suggest the flexible layer is affixed to the first surface of the substrate by an adhesive layer. The Examiner disagrees with Appellants assertion that the use of "comprising" is immaterial. Cottingham teaches the instantly claimed apparatus as detailed in the rejection above. What is immaterial is the number of layers disclosed by Cottingham because the term "comprising" applied to the apparatus of the instantly claimed invention means the apparatus can also have additional layers or elements. So even if Cottingham has a third layer, in addition to the two layers which anticipate the current claims, Cottingham anticipates these claims because the apparatus components are open, and may include additional elements.

Appellant further submits Cottingham does not disclose or suggest an array of biomolecules or probes positioned on said first surface within said reaction volume, but rather teaches "a rectangular array of discrete sample cells which contain a dried DNA amplification reagent." These cells are described at pages 10-11 of the Cottingham, et al. reference, and are designed to be discrete cells that are separated from each other by sealing strips on the sides. Thus, unlike the instant invention, wherein "an array of

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biomolecular probes is positioned on said first surface within said reaction volume,” in the Cottingham, et al. reference a series of separate reaction volumes is positioned on the first surface. Appellants argue this is different from the instant invention. The Examiner asserts Cottingham discloses the instant invention of “an array of biomolecular probes positioned on said first surface within said reaction volume” Cottingham discloses by Appellants admission, in the first full paragraph on p. 8 of Appellants brief, an array of discrete sample cells (or reaction volumes) which contain a dried DNA amplification reagent, the amplification reagent being nucleic acid primers which meet the limitation of biomolecular probe. Based on the disclosure of Cottingham the Examiner fails to see how Cottingham differs from the instantly claimed invention.

Obviousness rejection

Appellant relies upon overcoming Cottingham in order to overcome the obviousness rejection. If Cottingham is upheld as anticipatory, the obviousness rejection will stand. If Cottingham is reversed, then the obviousness rejection necessarily falls.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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